

Express Mail Label No. EL209599012US  
U.S. National Phase Entry of PCT/GB00/01104  
“Vaccine Composition”  
Filed: 20 September 2001  
PRELIMINARY AMENDMENT

- Part A1*
- C) cationic pluronics which are block copolymers or surfactants which are positively charged, in particular with NH<sub>2</sub><sup>+</sup> groups
  - D) complexing agents which form complexes with fatty acids such as deoxycholic acid, or
  - E) cyclodextrins and their derivatives such as dimethyl β cyclodextrin.

*Part A2*

5. (Amended) A composition according to claim 1 wherein the carrier comprises a particle.

10. (Amended) A composition according to claim 7 wherein the microsphere comprises poly-(L-lactide).

11. (Amended) A composition according to claim 1 wherein the ratio of the chemical (ii) to the carrier is from 99:1 to 9:1 w/w.

12. (Amended) A composition according to claim 1 which is adapted for administration to a mucosal surface or is suitable for parenteral administration.

*a3*

15. (Amended) A method of protecting a mammal against infection, which method comprises administration of a composition according to claim 1 to a mammal.

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*A4*  
20. (Amended) A microsphere according to claim 18 which further comprises  
an agent that is capable of generating a protective immune response in an animal to which it  
is administered.

*A5*  
22. (Amended) A pharmaceutical composition comprising a microsphere  
according to claim 19.

Respectfully submitted,



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Marked up version of claims showing changes made

3. (Amended) A composition according to claim 1 [or claim 2] wherein the said adjuvant chemical can act as an immunostimulant.

4. (Amended) A composition according to [any one of the preceding] claim[s] 1 wherein the said adjuvant chemical is selected from one or more of;

- A) poly-ornithine, for example of molecular weight from 5 to 150kDa;
- B) water soluble vitamins or vitamin derivatives such as vitamin E TPGS (d-alpha tocophenyl polyethylene glycol 1000 succinate),
- C) cationic pluronic which are block copolymers or surfactants which are positively charged, in particular with NH<sub>2</sub><sup>+</sup> groups
- D) complexing agents which form complexes with fatty acids such as deoxycholic acid, or
- E) cyclodextrins and their derivatives such as dimethyl β cyclodextrin.

5. (Amended) A composition according to [any one of the preceding] claim[s] 1 wherein the carrier comprises a particle.

10. (Amended) A composition according to [any one of] claim[s] 7 [to 9] wherein the microsphere comprises poly-(L-lactide).

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11. (Amended) A composition according to [any one of the preceding] claim[s]  
1 wherein the ratio of the chemical (ii) to the carrier is from 99:1 to 9:1 w/w.

12. (Amended) A composition according to [any one of the preceding] claim[s]  
1 which is adapted for administration to a mucosal surface or is suitable for parenteral  
administration.

15. (Amended) A method of protecting a mammal against infection, which  
method comprises administration of a composition according to [any one of] claim[s] 1 [to  
13] to a mammal.

20. (Amended) A microsphere according to claim 18 [or claim 19] which  
further comprises an agent that is capable of generating a protective immune response in an  
animal to which it is administered.

22. (Amended) A pharmaceutical composition comprising a microsphere  
according to [any one of] claim[s] 19 [to 22].